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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,326	03/20/2006	Stan Gronthos	75191/JPW/JW	6525

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EXAMINER	
HIRIYANNA, KELAGINAMANE T	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
04/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,326	GRONTHOS ET AL.	
	Examiner	Art Unit	
	KELAGINAMANE T. HIRIYANNA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *131-191* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *131-191* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
The inventions in claim 131-191 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 because the general technical feature namely the utilization of MPCs (Stro1+ cells in vascular repair) in tissue repair, that links the invention has been described in the prior art (see for example Dennis et al., Cells Tissues Organs, 2002; 170:73-82 and Hoerstrup et al, Circulation. 2002; 106{supl I}:I143-I150.). The invention comprises multiple methods involving compositions, the structure of which are distinct and used under distinct conditions. The distinct methods require independent search that are not co-extensive and is burdensome to examine together. Hence a restriction of the invention is proper. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 131-171, Method of inducing formation of blood vessels comprising administering an enriched population of cells that express the marker Stro-1.

II. Claims 131-171, Method of inducing repair of blood vessels comprising administering an enriched population of cells that express the marker Stro-1.

III. Claims 172, 175-181 and 183-186, Method of inducing formation of blood vessels comprising cultured or expanded enriched population of cells that express the marker Stro-1.

IV. Claims 172, 175-181 and 183-186, Method of inducing repair of blood vessels comprising cultured or expanded enriched population of cells that express the marker Stro-1.

V. Claims 173-174, 182 and 187-191, Method of inducing the repair of blood vessels in a patient suffering from disease associated with loss of alpha smooth muscle actin from vasculature comprising cultured or expanded enriched population of cells that express the marker Stro-1.

Note: Claim 187 is improper as it depends on itself. Claims 188-191 are objected-to as they are dependent on an improper dependent claim. Applicant must clarify the status indicate the proper dependence before being examined. Tentatively all these claims are included in invention V.

Species Election/Restrictions

This application further contains claims directed to the following patentably distinct species:

A. Applicant is required to elect a single species of enriched population of MPCs capable forming a clonogenic colony recited claims 135-136 i.e., 0.01% MPC or 1% MPC.

B. Applicant is required to elect a single species of enriched population of STRO-bright MPCs recited in claims 137-139 i.e., 0.01% STRO-bright MPCs or 0.1% STRO-bright MPCs or 1% STRO-bright MPCs.

C. Applicant is required to elect a single species of marker among the markers recited in claim 141 i.e., 3G5 or MUC18/CD46 or alpha-smooth muscle actin.

D. Applicant is required to elect a single species of marker among the markers recited in claim 142 i.e., THY-1 or VCAM-I or ICAM-I or PECAM-I or CD49a/CD49b/CD29 or CD49c/CD29 or CD49d/CD29 or CD29 or CD61 or integrin beta5 or 6-19 or thrombomodulin or CDI0 or CDI3 or SCF or PDGF-R or EGF-R or IGF-IR or NGF-R or FGF-R or Leptin-R (STRO-2).

E. Applicant is required to elect a single species of the source tissue of enriched population of cells recited in claim 144i.e., adipose tissue or teeth or dental pulp or skin or liver or kidney or heart or retina or brain or hair follicles or intestine or lung or

spleen or lymph node or thymus or pancreas or bone or ligament or bone marrow or tendon or skeletal muscle.

F. Applicant is required to elect a single species of enriched population of MPCs capable forming a clonogenic colony recited claims 148-149 i.e., 0.01% MPC or 1% MPC.

G. Applicant is required to elect a single species of enriched population of STRO-bright MPCs recited in claims 150-152 i.e., 0.1% STRO-bright MPCs or 1% STRO-bright MPCs or 10% STRO-bright MPCs.

H. Applicant is required to elect a single species of condition of patient in need of treatment among the recited in claim 161 i.e., cerebrovascular ischemia or renal ischemia or pulmonary ischemia or limb ischemia or ischemic cardiomyopathy or myocardial ischemia.

I. Applicant is required to elect a single species of cardiaovascular disease among the recited in claim 163 i.e., ischemic heart disease or coronary artery disease or acute myocardial infarction or congestive heart failure or cardiomyopathy or angina.

J. Applicant is required to elect a single species of cell introduction method among the recited in claim 164 i.e., localized injection or systemic injection or in a patch or on a stent.

K. Applicant is required to elect a single species of cell administration method among the recited in claim 165 i.e., intracoronary catheter or by intramyocardial or transepicardial or transendocardial.

L. Applicant is required to elect a single species of blood vessel repair method among the recited in claim 172 i.e., repair in order to generate new blood vessel or to repair existing blood vessels.

M. Applicant is required to elect a single species of enriched population of MPCs capable forming a clonogenic colony recited claims 175 and 176 i.e., 0.01% MPC or 1% MPC.

N. Applicant is required to elect a single species of enriched population of STRO-bright MPCs recited in claims 177 and 178 i.e., 0.01% STRO-bright MPCs or 1% STRO-bright MPCs.

O. Applicant is required to elect a single species of marker among the markers recited in claim 182 i.e., THY-1 or VCAM-I or ICAM-I or PECAM-I or CD49a/CD49b/CD29 or CD49c/CD29 or CD49d/CD29 or CD29 or CD61 or integrin beta5 or 6-19 or thrombomodulin or CDI0 or CDI3 or SCF or PDGF-R or EGF-R or IGF-IR or NGF-R or FGF-R or Leptin-R (STRO-2).

P. Applicant is required to elect a single species of the source tissue of enriched population of cells recited in claim 184 i.e., adipose tissue or teeth or dental pulp or skin or liver or kidney or heart or retina or brain or hair follicles or intestine or lung or spleen or lymph node or thymus or pancreas or bone or ligament or bone marrow or tendon orskeletal muscle.

Q. Applicant is required to elect a single species of enriched population of MPCs capable forming a clonogenic colony recited claims 187 and 188 i.e., 0.01% MPC or 1% MPC.

R. Applicant is required to elect a single species of enriched population of STRO-bright MPCs recited in claims 189-190 i.e., 0.1% STRO-bright MPCs or 1% STRO-bright MPCs or 10% STRO-bright MPCs.

The species are independent or distinct because they involve different structures and/or method steps.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 131 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.,* whose telephone number is (571) 272-3307. The examiner can normally be reached Monday through Friday from 9 AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.,* may be reached at (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system,

contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

Kelaginamane T. Hiriyanna
Patent Examiner
Art Unit 1633

/Robert M Kelly/

Primary Examiner of Art Unit 1633

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/551,326	GRONTHOS ET AL.	
	Examiner	Art Unit	
	KELAGINAMANE T. HIRIYANNA	1633	